

K. 510(k) Summary

Applicant's Name, Address, Telephone, FAX, Contact Information

Advanced Sterilization Products
A Johnson & Johnson Company
Division of Ethicon, Inc.
33 Technology Dr.
Irvine, CA 92618

Contact Person:

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Submission Date

August 18, 2008

Trade Name

EVOTECH™ Endoscope Cleaner and Reprocessor

Common Name

Washer Disinfector

Classification

Class II

Legally Marketed Equivalent Device

EVOTECH™ Endoscope Cleaner and Reprocessor (K061899)

Description of Device

The EVOTECH™ Endoscope Cleaner and Re-processor was cleared under the Premarket Notification process (K040883) found substantially equivalent on March 15, 2005. Subsequent to that the EVOTECH ECR was granted a cleaning claim in Premarket Notification K061899 (found substantially equivalent on October 26, 2006).

The system is designed to clean and disinfect endoscopes. The system performs tests to check for connection of endoscopes, for leaks in endoscopes, and for blockage of lumens. The device will clean and high-level disinfect endoscopes and provides for automated alcohol flush of the lumens. The system

also has a self-disinfection cycle that can be selected (recommended to be performed every 5 days) to prevent the build up of biofilm in fluid pathways.

Indications for Use

The EVOTECH™ System, a washer/disinfector, is indicated for use with high-level disinfectant CIDEX® OPA Concentrate and an enzymatic detergent (CIDEZYME GI) to achieve cleaning and high level disinfection of heat sensitive (>60°C) semi-critical endoscopes. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EvoTech System when selecting those cycles that contain a wash stage. (Manual cleaning of medical devices (endoscopes) is required when selecting the Disinfect only or Disinfect/Alcohol Flush Cycle.)

Description of Modification

Several subsystems have been modified in order to increase reliability of the device. No changes to the device have been made that will affect the cleaning and high-level disinfection performance of the device.

Summary of Non-clinical Tests

Verification of all physical and electrical changes were done to ensure that they did not affect the performance of the device with respect to cleaning and high-level disinfection. Non-clinical testing was not done since risk analysis of the changes did not implicate a change to performance with respect to cleaning and high-level disinfection claims.

Changes to critical parts were evaluated.

Disinfectant dispenser-

The change was made after determining that the material was compatible with CIDEX OPA Concentrate Solution and that the change did not impact the performance to this part, i.e. it met the specification for dispensing volume and reproducibility.

Spray arm guard-

The addition of the spray arm guard was evaluated to show that it did not impact the rotation of the arm or affect the spray pattern and hence would not affect the cleaning and disinfection performance of the device.

MEC Monitor-

A manufacturing change to the MEC monitor detector was made and evaluated for performance. Data indicate that the performance is equivalent to the previous device.

Lid Motor Control-

Changes to the circuitry of the lid motor driver were made so that the lid would not open while the machine was in operation. This was to prevent a potential safety issue.

Software was validated for the changes made.

Substantial Equivalence

Based on the data obtained from the studies described above, the Modified Device, EVOTECH™ Endoscope Cleaner and Reprocessor is substantially equivalent to the Predicate Device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Advanced Sterilization Products
A Johnson & Johnson Company
Division of Ethicon, Incorporated
Joseph M. Ascenzi, Ph.D., RAC
Senior Manager, Regulatory Affairs
33 Technology Drive
Irvine, California 92618

Re: K082392

Trade/Device Name: EVOTECH™ Endoscope Cleaner and Reprocessor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FEB
Dated: October 13, 2008
Received: October 14, 2008

Dear Dr. Ascenzi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082392

Device Name: EVOTECH™ Endoscope Cleaner and Reprocessor

Indications for Use:

The EVOTECH™ Endoscope Cleaner and Reprocessor, a washer/disinfector, is indicated for use with high- level disinfectant CIDEX® OPA Concentrate and an enzymatic detergent (CIDEZYME GI) to achieve cleaning and high level disinfection of heat sensitive (>60°C) semi-critical endoscopes. Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EVOTECH System when selecting those cycles that contain a wash stage. (Manual cleaning of medical devices (endoscopes) is required when selecting the Disinfect only or Disinfect/Alcohol Flush Cycle.)

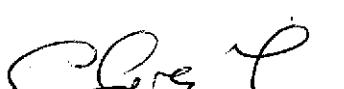
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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